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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/723,323 | 11/26/2003 | Enrico Alessi | 64659-00003USPX | 9467 |

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| EXAMINER | |
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| LIN, JERRY | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/723,323 | ALESSI ET AL. | |
| | Examiner | Art Unit | |
| | Jerry Lin | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☑ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 page (1/26/2006)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, and claims 5 and 8 in the reply filed on June 27, 2006 is acknowledged. The Applicants have amended the instant claims and have traversed on the grounds that the Apparatus in Group II cannot be used to perform a different process than group I. Applicants also traversed the Species election on the grounds that claim 5 is now dependent on claim 4. Applicants also traversed the Subspecies election regarding claims 8-12 on the grounds that the claims overlap in scope. The Applicants' traversal is found persuasive as it relates to the Groups and the Species. Thus claims 1-8, 13, and 14 will be rejoined. However, the Applicants' traversal of the subspecies regarding claims 8-12 are not persuasive. This is not found persuasive because the subspecies do not overlap in scope. Applicants argue that the subspecies overlap in scope because each of the claims is related to overall/global coefficients. However, sharing subject matter does not indicate a sharing of scope. In the instant case, each of the claims refers to a different method of calculating coefficients. Since each claim details different steps and the steps define a method, the instant claims do not share the same scope.

The requirement is still deemed proper and is therefore made FINAL.

### *Status of the Claims*

Claims 1-8, 13, and 14 are under examination.

Claims 9-12 are withdrawn from examination as being drawn to an unelected invention.

***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

3. The item listed as C7 "European Search Report" on the IDS filed January 26, 2004 has not been considered, because the reference is not a published document.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Instant claims 1 and 13 recite the term " 'Gene Networks' ". This term is not commonly accepted in the art nor is there an explicit definition of the term in the specification. Furthermore, the presence of quotation marks around the term seem to indicate that this term has a particular meaning for this application, however, that meaning is not disclosed. The specification does mention one embodiment of " 'Gene

Networks' ", on page 6, paragraph 36, as groups of genes likely involved in a cellular process. However, this is not a definition and is only one embodiment of the term.

7. Instant claim 5 was amended to include the limitation of "and wherein the parameters having a semantic biological meaning . . .. " It is unclear if the instant claim is requiring that one numeric parameter and one semantic biological meaning is required or if only one numeric parameter or semantic meaning is required. Since claim 4, from which claim 5 depends only requires only one numeric parameter or semantic meaning, this interpretation will be used for purposes of this office action.

8. Regarding claim 6, it is unclear what "considering" in line 3 means. One interpretation of "considering" is that the gene is only inputted into the clustering algorithm once. Another interpretation of "considering" is that the parameters are only calculated once from that gene.

### *Claim Rejections - 35 USC § 101*

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a mathematical algorithm for clustering gene datasets that includes clustering data, pairing datasets, calculating parameters of paired datasets, determining a value based on the parameters, and identifying pairs with values greater than a threshold.

In regards to claims 1-8, the instant claims are drawn to a mathematical algorithm. A mathematical algorithm is non-statutory unless the claims include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It is important to note, that the claims themselves must include a physical transformation step or an useful, tangible and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not include any tangible result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. However, the instant claims do not arrive a

real world result. Rather, the instant claims end with a final process, the process of identifying. This does not necessarily lead to a result. Since the instant claims do not necessarily lead to a result, the instant claims do not include any tangible result.

### *Claim Rejections - 35 USC § 103*

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-7, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shamir et al. (US 2003/0224344) in view of Dougherty et al. (Journal of Computation Biology (January 2002) Volume 9, Number 1, pages 105-126) further in view of Tolley (US 2004/0128080).

The instant claims are drawn to a method of clustering wherein a dataset is clustered in to smaller datasets, the smaller datasets are paired, characteristic parameters of the pairs are calculated, a value is generates as a function of the parameters, and pairs with values greater than a threshold are identified as "Gene Networks" and pairs with values lower than a threshold are discarded.

Regarding claims 1 and 13, Shamir et al. teach a method of clustering wherein a dataset is clustered (data is generated in relation to time or environmental conditions)(page 1, paragraph 0004-0008; page 2, paragraph 0011-0021); where groups of genes satisfy a clustering criterion (page 2, paragraph 0011-0021); establishing pairs of sub-tables (clusters) (page 2, paragraph 0015-0017); calculating the parameters of the data in each pair combination (page 2, paragraph 0015-0017); and identifying pair combinations whose values is greater than a threshold as "Gene Networks" (genes involved in the same cellular process) and discarding combination (not clustering together) genes whose values are smaller than a threshold (page 2, paragraph 0015-0017). Shamir et al. also teach outputting the results (page 8, paragraph 0102).

However, Shamir et al. do not disclose using a decision algorithm based on soft computing or wherein the datasets are presented in tables.

Regarding claims 1 and 13, Tolley teaches using clustering algorithms on datasets that are presented in tables (page 7, paragraph 0059-0062).

Regarding claims 1, 3 and 13, Dougherty teaches that data may be clustered using a variety of soft computing techniques including fuzzy logic (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of Shamir et al., Dougherty et al. and Tolley to incorporate the benefits of fuzzy logic in the method of Shamir et al. Shamir et al. states that their goal is to create a more accurate clustering method (page 2, paragraph 0021). Shamir et al. attempt to create a more accurate clustering method by introducing more weights to a clustering means (page 2, paragraph 0021). Dougherty et al. is also concerned with improving the accuracy of clustering algorithms (abstract). In order to determine the best clustering algorithms, Dougherty et al. compares several known techniques. The find that Fuzzy logic as one of the means that has more accuracy than other means (page 118-page 120, top). Thus, one of ordinary skill in the art seeking to improve the accuracy of clustering algorithms would be motivated to combine the methods of Dougherty et al. and Shamir et al., since each method improves different components of a clustering algorithm. Furthermore, Tolley teaches that database are typically organized in tables (page 7, paragraph 0057). Thus one of ordinary skill in the art would expect to perform the method of Dougherty et al. and Shamir et al. on a database organized in tables.

Regarding claim 2, Shamir et al. teach using a logic filtering criteria (page 5, paragraphs 0051-0054; page 8, paragraph 0101).

Regarding claim 4, Shamir et al. teach wherein the parameter is tied to gene expression levels (page 1, paragraph 0006).

Regarding claim 5, Shamir et al. teach wherein the parameter is a correlation coefficient (page 5, paragraph 0054; page 8, paragraph 0095).

Regarding claim 6, Shamir et al. teach wherein low degree vertices (low number of genes) are eliminated (page 2, paragraph 0018-0019).

Regarding claim 7, Dougherty et al. disclose using SOM or K-means clustering (page 1118).

Regarding claim 14, Dougherty et al. teach training the fuzzy logic not using any on-line capabilities (page 124).

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have

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MICHAEL BORIN, PH.D
PRIMARY EXAMINER

JL